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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,701

11/12/2003

Paul Lehmann

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151 7590 04/30/2008

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
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EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,701	Applicant(s) LEHMANN ET AL.	
	Examiner HOPE A. ROBINSON	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-14 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's response to the Office Action mailed September 13, 2007 on October 5, 2007 is acknowledged.
2. Claims 1-2 and 5-14 are pending and are under examination.
3. The following rejections are or remain applicable.

Basis For NonStatutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 5-14 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-15 of copending Application No. 11/013,560. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from heart disease comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin that is epoetin alfa or beta (claim 3); SEQ ID NO:1 (claim 4); a modification of 1 to 6 glycosylation sites (claim 5); a darbepoetin (claim 6); pegylated (claim 7); and a conjugate having a particular structure as set forth in claims 8-14. The copending application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from chronic inflammatory intestinal disease comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin

that is epoetin alfa or beta (claim 4); SEQ ID NO:1 (claim 5); a modification of 1 to 6 glycosylation sites (claim 6); a darbepoetin (claim 7); pegylated (claim 8); and a conjugate having a particular structure as set forth in claims 9-15. The instant application claims differ from the copending application in that the patient is suffering from heart disease, whereas the copending application patient is suffering from chronic inflammatory intestinal disease, however, the methods have one step, administering erythropoietin, thus the resulting effect will be the same. Thus, the two sets of claims differ in scope but are obvious one over the other, as the intended use does not materially change the composition administered.

6. Claims 1 and 5-14 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-15 and 17-26 of copending Application No. 10/634,477. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from heart disease comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an

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erythropoietin that is epoetin alfa or beta (claim 3); SEQ ID NO:1 (claim 4); a modification of 1 to 6 glycosylation sites (claim5); a darbepoetin (claim 6); pegylated (claim 7); and a conjugate having a particular structure as set forth in claims 8-14. The copending application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from diabetes comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin that is epoetin alfa or beta (claim 3); SEQ ID NO:1 (claim 4); a modification of 1 to 6 glycosylation sites (claim5); a darbepoetin (claim 6); pegylated (claim 7); and a conjugate having a particular structure as set forth in claims 8-12. The instant application claims differ from the copending application in that the patient is suffering from heart disease, whereas the copending application patient is suffering from diabetes, however, the methods have one step, administering erythropoietin, thus the resulting effect will be the same. Moreover, the art generally recognizes that heart disease is a risk with diabetes, for example type II diabetes. Thus, the two sets of claims differ in scope but are obvious one over the other, as the intended use does not materially change the composition administered.

Response to Arguments

7. The response filed has been considered however not deemed persuasive, therefore the provisional double patenting rejections remain since no terminal disclaimer was filed and the claim amendments did not obviate this ground of rejection.. Applicants traverses the ODP rejections over application 11/013,560 stating that the patient pool is not coextensive with the

subject matter of the instant application. It is further stated that one does not necessarily equate treatment of chronic inflammatory intestinal diseases with heart diseases accompanied by iron distribution disturbances.

At the outset it would appear that applicants are on point in terms of the patient population being different, however, the claims in both application are directed to a "a method of treating disturbance in iron distribution" by administering human EPO (SEQ ID NO:1). The two sets of claims differ in that one patient population has heart disease and the other has inflammatory intestinal disease, thus the two differ in scope. Applicant is reminded that the obvious type double patenting rejection follows a 103 analysis. The art recognizes that inflammatory intestinal disease is associated with anemia (iron deficiency can cause an iron distribution problem). Furthermore, the art recognizes that there is some association between serum iron, transferrin saturation and heart disease. Thus, the diseases afflicting the patient pool described in the instant application and the copending application have been associated with iron distribution problems and thus, both populations would be in need of treatment with EPO. Although, the scope of the two sets of claims differ, the two sets of claims are obvious variations because the objective of the method is to treat disturbances in iron distribution, not heart disease or inflammatory intestinal disease. As both diseases have an underlying disturbance in iron distribution, the two sets of claims are obvious with a method of treatment solely by administration of EPO.

With regard to application 10/634,477, applicant traverses the rejection and state that the fact that heart disease and diabetes may sometimes be associated with each other does not de facto mean that they always are or what works as an effective therapy for one condition would be

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expected to work for the other. Applicant's arguments have been considered but are not persuasive. The issue at hand is not a treatment/medicament for heart disease or diabetes, but a treatment for disturbances of iron distribution in two different patient population, that have been shown to be related in the office action. The art recognizes that diabetes is an important risk factor for the development of cardiovascular disease, this is a known fact. Thus, the relationship between the two diseases is not speculative or as stated by applicant, "may sometimes be associated". Further, diabetes is associated with iron distribution problems as well in the art, in terms of excessive tissue iron stores which is recognized as a contributor to the occurrence and complications of diabetes. The obvious type double patenting rejections remain over both applications because the methods in each application is directed to treating disturbances in iron distribution by administering EPO, the methods in deed have a different patient population, however the administration of EPO is not to treat the disease that brings about the difference in each population, but instead is used to treat the iron problem, and each population would necessarily require the administration of EPO since the art recognizes that they each have an underlying iron problem. Furthermore, diabetes is a known risk factor for heart disease. Thus, the rejection remains since no TD was filed.

Conclusion

8. No claims are allowable and claim 2 is objected to as depending from a rejected based claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652